Response to Applicant's Remarks

The restriction requirement of 27 February 2009 is hereby made final.

Applicant's response on February 5, 2010 filed in response to Non-Final Office Action dated October 5, 2009 has been received and duly noted.

In view of this response, the status of the rejections/objections of record is as follows:

Status of the Claims

Claims 1 and 3 are pending and rejected.

Claim 2 has been cancelled.

Claim 3 is directed towards non-elected subject matter and is withdrawn from consideration.

35 USC § 112 Rejection(s)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The 112-1st rejection of claims 1 (claim 2 has been cancelled) regarding the scope of enablement have not been overcome in view of Applicant's amending the claims by deleting the terms "monocyclic or polycyclic alicyclic hydrocarbon groups, monocyclic or polycyclic hydrocarbon groups or heterocyclic groups". Examiner

indicated that Applicant was not enabled for X1 and X2 being any variable other than OH; R6 for being any variable other than unsubstituted phenyl; R7 for being any variable other than alkyl, H, unsubstituted phenyl and benzyl; R1 and R2 for being any variable other than t-butyl; and R3 and R4 for being any variable other than H and alkoxy. Applicant argues that the following variables show support as indicated by in the Specification:

> Claim 1 has been amended to further specify the composition of various groups in the formulae. Support is as follows:
>
> As to R^3: See page 5 line 9 of the specification.
>
> As to R^4: See page 5 lines 10-11 of the specification.
>
> As to R^3 and R^4 together: See examples 4, 5, 6, 7, 8, 10 and 11, in which in each case R^3 and R^4 together with the carbon atoms to which they are bonded form an indene, 1,2-dihydronaphthalene, cyclohexene, cycloheptene or cyclopentene ring. Please note that the phrase "with the carbon atoms to which they are bonded" has been added here, to more accurately and specifically describe the compounds. This is fairly supported by the examples just mentioned; in each case the ring structure includes the carbon atoms to which the R^3 and R^4 groups are attached.
>
> As to R^7: See page 5 lines 12-13 of the specification.
>
> As to R^8: See page 5 lines 15-17 of the specification.
>
> As to X^1 and X^2: See page 4 line 7 of the specification.

However, this argument does not properly address the 112-1st rejection regarding enablement as clearly described in previous Non-Final rejection.

Applicant has pointed to particular sections of the Specification where support can be found for enablement of variables R1, R2, R6, R7, X1 and X2. However, said sections of the Specification only shows written support for R1, R2, R6, R7, X1 and X2, but does not teach one skilled in the art how to make and/or use the full scope of the

claimed invention without undue experimentation. Examiner indicated in previous Office Action that R6 being unsubstituted phenyl; R7 being methyl, ethyl, H, unsubstituted phenyl, benzyl and OSiTB; and X1 and X2 being OH. Applicant has not provided support in the Specification regarding how to make optically active hydroxylated compounds using compounds of chemical formulae 1 and 2 where R6/R7 is "aryl" and X1/X2 is SR10 and NR11. There are no guidances on how to perform the claimed invention with indicated variables.

Claim Rejections Withdrawn

The 112-1st rejection of claims 1 (claim 2 has been cancelled) regarding the written description of the terms "monocyclic or polycyclic alicyclic hydrocarbon groups, monocyclic or polycyclic hydrocarbon groups or heterocyclic groups" have been overcome in view of Applicant's deleting such terminology from the claims.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for, R6 being unsubstituted phenyl, R7 being phenyl

and benzyl; and R1/R2 being t-butyl, but does not reasonably provide enablement for R1/R2 and R6/R7 being the term "aryl."

Pursuant to *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), one considers the following factors to determine whether undue experimentation is required: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. Some experimentation is not fatal; the issue is whether the amount of experimentation is "undue"; see *In re Vaeck*, 20 USPQ2d 1438, 1444.

The analysis is as follows:

(1) Breadth of claims: Scope of the compounds and a method of producing optically active compounds using compounds of chemical formulae 1 and 2.

(2) The nature of the invention: The invention is a highly substituted silicon enolate compounds of formula 2, bipyridyl compounds of formula1 and hydroxymethylated compounds being produced.

(3) Level of predictability in the art: It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and chemical

reactivity (which is affected by determinants such as substituent effects, steric effects, bonding, molecular geometry, etc) is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

(4) Direction or Guidance: That provided is very limited. Applicant shows a general synthesis of compounds of application's general formula I. Pages 4-9 of the Specification describes starting materials and methods for synthesis of compounds wherein R6 being unsubstituted phenyl, R7 being phenyl and benzyl; and R1/R2 being t-butyl as described above, but does not describe or list any reagents wherein compounds can be used to synthesis compounds where R1/R2 and R6/R7 being the term "aryl."

There is limited evidence in the Specification of the example compounds that only covers no or a small portion of the substituents claimed of formula. Thus, there is no specific direction or guidance regarding said compounds specifically mentioned in Scope.

The definition of the term "aryl" is an organic radical derived from an aromatic compound by the removal of one hydrogen atom (see http://medical-dictionary.thefreedictionary.com/p/aryl). In the context of organic molecules, the term "aryl" refers to any functional group or substituent derived from a simple aromatic ring, which may be phenyl, thiophenyl, indolyl, pyridyl, etc. "Aryl" is used for the sake of abbreviation or generalization.

The term “aryl” group covers much more than the unsubstituted phenyl and benzyl variables for which Applicant shown above due to Applicant’s lack of defining the term "aryl". For further guidance of chemical nomenclature, Examiner suggest Applicant refer to the International Union of Pure and Applied Chemistry website (http://www.iupac.org/).

The availability of the starting material that is needed to prepare the invention as claimed is at issue here…As per MPEP 2164.01 (b). A key issue that can arise when determining whether the specification is enabling is whether the starting materials or apparatus necessary to a make the invention are available. In the biotechnical area, this is often true when the product or process requires a particular strain of microorganism and when the microorganism is available only after extensive screening. The Court *in re Ghiron*, 442 F.2d 985, 991, 169 USPQ 723, 727 (CCPA 1971), made it clear that if the practice of a method requires a particular apparatus, the application must provide a sufficient disclosure of the apparatus if the apparatus is not readily available. The same can be said if certain chemicals are required to make a compound or practice a chemical process. *In re Howarth*, 654 F.2d 103, 105, 210 USPQ 689, 691 (CCPA 1981).

It is not trivial to experimentally interchange any and all of the many substituents that exist. As described by F. Zaragoza Dörwald, most organic syntheses fail initially and chemical research is highly inefficient due to chemists spending most of their time

"finding out what went wrong and why". Therefore, most syntheses of organic compounds are labor-intensive and demanding. Additionally, most final synthetic routes to desired organic molecules are usually very different from initially planned routes. A highly skilled chemist can agree that for many successful organic compounds made, many failures are encountered and experimental repetition is common. This also contributes to the burden and unpredictability of the syntheses of said compounds. (see “Side Reactions in Organic Synthesis: A Guide to Successful Synthesis Design" 2005 Wiley-VCH Verlag GmbH & Co. KGaA, Weinheim.

(6) Working Examples: Applicant shows examples 1-14 (chart on page 9) but no working examples were shown wherein R1/R2 and R6/R7 equal aforementioned substituents have been made or used of any kind.

(7) Skill of those in the art: The ordinary artisan is highly skilled, e.g. a masters or PhD level chemist.

(8) The quantity of experimentation needed: Since there are very limited working examples as described above, the amount of experimentation is expected to be high and burdensome.

Due to the level of unpredictability in the art, the very limited guidance provide, and the lack of working examples, the Applicant has not provided sufficient guidance for the artisan to make the invention.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1.

Double Patenting

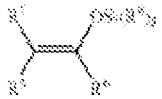
The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

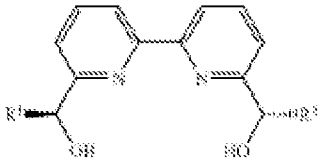
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4 and 6-8 of U.S. Patent No. 7,541,307. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following.

US '307 claims a method of manufacturing a process of producing an optically hydroxymethylated compound comprising a silicon enolate of below



and a bipyridine catalyst of



where R3 and R4 = H, alkyl, alkoxy; X1 and X2 = hydroxyl and R1 and R2 = H, alkyl.

Conclusion

No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Mabry, PhD whose telephone number is (571) 270-1967. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Janet Andres, PhD, can be reached at (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/John Mabry/
Examiner
Art Unit 1625

/Janet L. Andres/
Supervisory Patent Examiner, Art Unit 1625